



March 15, 1999

1270 '99 MM 23 P2:14

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204 3/1/9

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement within the last thirty days under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Korean Ginseng: For energy and endurance. Korean Ginseng (also called Panax Ginseng) has the unique ability to vitalize, strengthen and rejuvenate the entire body. It also helps the body to utilize oxygen, which enhances recovery and helps the body adapt to and resist physical and environmental stress. To further promote sustained energy levels, take Sundown Standardized Korean Ginseng with Sundown B-Complex and Sundown CoQ-10. B-vitamins are essential for promoting sustained energy levels throughout the day. CoQ-10 plays a critical role in the production of energy in every cell of the body. Korean Ginseng has been honored for centuries for restoring vitality and the balanced state considered key to good health.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs and Assistant General Counsel

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Enclosure